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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,648	02/20/2004	Geoffrey N. Holland	7135USO7	7354

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EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3623	

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12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/783,648	HOLLAND ET AL.	
	Examiner	Art Unit	
	R. David Rines	3623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 October 2009 has been entered.

Notice to Applicant

[2] This communication is in response to the Amendment and the Request for Continued Examination (RCE) filed 15 October 2009. It is noted that this application benefits from Provisional Patent Application Serial Nos. 60/509,404 and 60/527,583 filed 7 October 2003 and 5 December 2003, respectively. Claims 4, 7-8, and 11-20 have been cancelled. Claims 1 and 10 have been amended. The Information Disclosure Statement (IDS) filed 15 October 2009 has been entered and considered. Claims 1-3, 5-6, 9 and 10 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[3] Claims 1-3, 5-6, and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to further include a step of: "…using program code in a rule set editor associated with the medication management unit, automatically pre-validating and displaying suggested corrections to drug library entries in real time as the entries are input into a new hospital-wide drug library by a user…". The functions intended by the added limitation are unclear. As drafted, it is unclear whether a user, "the medication management unit" or the "medical infusion device" is using code is "using program code...". Additionally, it is not clear whether the recited "using program code..." is functionally connected to the subsequent "automatically pre-validating..." (e.g., using program code *to* automatically pre-validate...). The claim limitation additionally introduces "entries" without a direct tie to the preceding steps. It is accordingly unclear whether "entries" are made "using the code..." or whether entries previously made are "validated and displayed by "using the code". For purposes of applying art, Examiner assumes that entries/changes are made to the drug library using the rule set editor (e.g., an

interface). However, this is not clear from the claim as presented and appropriate clarification/correction is required.

Claims 2-3, 5-6, and 9-10 inherit and fail to remedy the deficiencies of claim 1 through dependency and are rejected under 35 U.S.C. 112, second paragraph, for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[4] Claims 1-3, 5-6, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (United States Patent Application Publication #2006/0106649) in view of Ullestad et al. (United States Patent Application Publication #2004/0030323)

As per claim 1, Eggers et al. disclose a method for preparing a new hospital-wide drug library and downloading at least a portion thereof from a medication management unit to a medical infusion device of a given type having a primary memory and an existing drug library stored in the primary memory, comprising: preparing a new hospital-wide drug library and downloading at least a portion thereof from a medication management unit to a medical infusion device of a given type having a primary memory and an existing drug library stored in the primary memory, comprising: determining that a drug library update needed event has occurred (Eggers et al.; paragraphs [0034] [0036] [0057] [0063] *see change location and new library *Examiner considers the total drug library to be a "hospital-wide library" and the location specific drug libraries to be a "portion of" the library); transmitting a new drug library from the medication management unit to the medical infusion device upon occurrence of the drug library update needed event (Eggers et al.; paragraphs [0034] [0057] *see location specific configuration database); storing the new drug library in a memory of the medical infusion device while maintaining the existing drug library in the primary memory (Eggers et al.; paragraphs [0057] [0070]); determining that a specific trigger event has occurred (Eggers et al.; paragraphs [0034] [0057]); and replacing the existing drug library in the primary memory with the new drug library upon occurrence of the trigger event (Eggers; paragraphs [0034] [0057]).

Claim 1 has been amended to further include the step of "...using program code in a rule set editor associated with the medication management unit, automatically pre-validating and displaying suggested corrections to drug library entries in real time as the entries are input into a new hospital-wide drug library by a user;..."

As per this element, Eggers et al. disclose an interface/programmer that allows facilitates the selection of device parameters (i.e., "entries") including the identification of the appropriate configuration database for the patient/intended protocol (Eggers et al.; paragraphs [0024] [0025] [0030] [0031] [0034] [0035]). Examiner considers this teaching to constitute using program code in a rule set editor associated with the medication management unit, automatically pre-validating and displaying suggested corrections to drug library entries in real time as the entries are input into a new hospital-wide drug library by a user, at least insofar as presently claimed.

Claim 1 has been amended with respect to the "transmitting" step to further specify; "...transmitting only any changed portion of the new hospital-wide drug library applicable to the given type from the medication management unit to the medical infusion device;..."

As per this element, Eggers et al. disclose accessing location and function specific configuration databases which include drug library information (Eggers et al.; paragraphs [0034]-[0036]). Eggers et al. further disclose that the drug libraries are segmented by treatment location and the specific sub-libraries/configurations are accessed based on location and patient-specifics (Eggers et al.; paragraphs [0034]-[0036]). Examiner considers the various configurations to be "changed portions" and the total drug library to constitute a "hospital-wide" library.

Claim 1 has been amended with respect to the "replacing" step to further specify: "...replacing the existing drug library in the primary memory with the transmitted portion of the new hospital-wide drug library upon occurrence of the trigger event...."

As per this element, Eggers et al. disclose continual updating and exchanging of configuration data from configuration databases as well as the primary memory of the device (Eggers et al.; paragraphs [0034] [0036] [0055] [0066] [0067]). Further, as also noted by Applicant, Eggers et al. disclose storing the configuration databases in various forms of memory and exchanging or updating the configuration data through retrieval of a specific data sets identified by an ID number (Eggers et al.; paragraphs [0034]-[0037] [0055] [0064] [0066]). Examiner considers this teaching to constitute "replacing the existing drug library in the primary memory with the transmitted portion of the new hospital-wide drug library upon occurrence of the trigger event, at least insofar as presently claimed by Applicant.

Claim 1 has been amended with respect to the "storing" step to further specify; "…storing the transmitted portion of the new hospital-wide drug library in a cache memory of the medical infusion device while maintaining the existing drug library in the primary memory;…"

As per this element, Eggers et al. disclose replacing as existing portion of the drug library in the memory of the device with a new configuration/drug library retrieved from the database (Eggers et al.; paragraphs [0034] [0036] [0055] [0066] [0067]). Eggers et al. disclose transferring the configurations from the database to the primary memory (i.e., from one memory to another) and Eggers et al. further disclose numerous forms of memory to be considered in the system (Eggers et al.; paragraphs [0024] [0033]). While Examiner considers the form of memory used prior to replacement of the configuration/library to be a design choice clearly appreciated in the disclosure of Eggers et al., Eggers et al. fail to specifically indicate that the new configuration is stored in "cache" memory.

However, the use of cache memory in medical pumps to store operating data/parameters in temporary memory prior to transfer into the primary memory is well known in the art as evidenced by Ullestad et al. (Ullestad et al.; paragraph [0033]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the transfer of pump configurations from storage memory to device primary memory of Eggers et al. with the well known use of cache memory as disclosed by Ullstead et al. with the motivation of employing a well-known computer memory structure to facilitate a

transfer of data and to further ensure valid changes and values for pump operating parameters prior to storage of the values in the primary memory of the device (Ullstead et al.; paragraphs [0032] [0033]).

As per claim 2, Eggers et al. disclose a method wherein the trigger event is selected from the group consisting of a completed infusion, a stopped infusion, a determination that the device is in a configurable mode, elapsed time, a specific date and time, creation of the new drug library, a download of a modified drug library to the medication management unit, and a determination that the existing drug library at the medical device needs updating (Eggers et al.; paragraphs [0034] [0057] [0063] see change configuration by location, patient, or updated library NOTE: The selection of additional trigger events to constitute a user choice that is accommodated by the Eggers disclosure).

Regarding claim 2, the conclusions obviousness and statements of motivation as discussed with regard to claim 1 above are applicable to claim 2 and are herein incorporated by reference.

As per claim 3, while Eggers et al. fail to specifically recite "power-on sleeping mode" and "power off mode", Eggers et al. considers device use states or operational modes as a trigger event for a configuration update or retrieval (Eggers et al.; paragraphs [0066]-[0068] *see "power on").

While Eggers et al. fails to explicitly state that sleep and power-off modes as utilized as the trigger events, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the "power on" trigger disclosed by Eggers et al. with well known alternative equipment modes with the motivation of installing the appropriate configuration data prior to initiating an infusion (Eggers et al.; paragraphs [0066]-[0068]).

Regarding claim 3, the conclusions obviousness and statements of motivation as discussed with regard to claim 1 above are applicable to claim 3 and are herein incorporated by reference.

Claim 4 has been cancelled.

As per claim 5, Eggers et al. disclose a method wherein the step of determining when the trigger event has occurred is done by the medication management unit (Eggers et al.; paragraphs [0034] [0056] [0057] [0063] *see patient specific parameters).

As per claim 6, Eggers et al. disclose a method wherein the step of determining when the trigger event has occurred is done by the medical device (Eggers et al.; paragraphs [0034] [0056] [0057] see location specific parameters).

NOTE: regarding claims 5-6, Examiner interprets the applied teachings of Eggers et al. to indicate that the type of trigger event dictates which networked device initiates the configuration change.

Regarding claims 5-6, the conclusions obviousness and statements of motivation as discussed with regard to claim 1 above are applicable to claims 5-6 and are herein incorporated by reference.

Claims 7 and 8 have been cancelled.

As per claim 9, Eggers et al. disclose a method further comprising the step of performing an infusion with the medical device using the existing drug library during the transmitting step (Eggers et al.; paragraphs [0034] [0051] [0057]).

As per claim 10, Eggers et al. disclose a method wherein the new drug library is stored in the cache memory while the medical device is performing an infusion (Eggers et al.; paragraphs [0034] [0051] [0057] [0070] see "multi-step").

Regarding claims 9-10, the conclusions obviousness and statements of motivation as discussed with regard to claim 1 above are applicable to claims 9-10 and are herein incorporated by reference.

Claims 11-20 have been cancelled.

Response to Arguments

Applicant's arguments filed 15 October 2009 have been fully considered by the Examiner and are considered moot in view of newly added grounds of rejection.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 15 October 2009 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Eggers et al. and Ullstead et al., based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (mailed 14 April 2009), and incorporated herein.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Martucci et al., MEDICATION DELIVERY SYSTEM, United States Patent #6,985,870.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David Rines whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/
Examiner, Art Unit 3623